Remarks

Claims 1-5, 9, 10, 12-17, 22, 27-30, 46-48 and 111 are pending in the subject application.

Restriction/Species Election

In the May 1, 2008 Office Action, the Examiner restricted pending claims 1-5, 9, 10, 12-17, 22, 27-30, 46-48 and 111 to one of the following allegedly distinct inventions under 35 U.S.C. §121 as follows:

I. Claims 1-5, 9-10, 12-17, 22 and 27-30, drawn to methods of treating disease or providing protection comprising administering glatiramer acetate and 2-amino-6-trifuoromethoxybenzathiazole;

II. Claims 46-48 and 111, drawn to pharmaceutical compositions and packages;

In response, applicants hereby elect with traverse Group I, i.e. claims 1-5, 9-10, 12-17, 22 and 27-30 for prosecution at this time.

Applicants note that 35 U.S.C. §121 states, in part, that "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require application to be restricted to one of the inventions." [Emphasis added]. Applicant requests that the restriction requirement be withdrawn in view of the fact that the claims of Groups I and II are not independent.

Under M.P.E.P. §802.1, "independent" means "there is no disclosed relationship between the subjects disclosed, that is, they are unconnected in design, operation, and

effect...". The claims of Group II are drawn to compositions useful in the methods recited by the claims of Group I. Therefore, Group I and II are related.

The Examiner further asserted that the inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical features for the following reasons: the first claimed technical feature is not a contribution over the prior art and therefore does not constitute a special technical feature as defined in PCT Rule 13. The Examiner alleged that Polman (WO 00/74676) teaches co-administration of glatiramer acetate and riluzole (2-amino-6-trifluoromethoxybenzathiazole) to patients with multiple sclerosis (page 2, lines 15-30 and page 3, lines 7-10). The Examiner asserted that as the first claimed technical feature is not a special technical feature, there can be no special technical feature which links all inventions.

Applicants note that Polman contains a laundry list of agents useful in treating multiple sclerosis which includes glatiramer acetate. Furthermore, applicants point out that the administration of two drugs to treat a given condition, such as a form of multiple sclerosis, raises a number of potential problems (see pages 5, line 33 to page 7, line 3 of the instant application). Specifically, it is well accepted that "...when two drugs are administered to treat the same condition, it is unpredictable whether each will complement, have no effect on, or interfere with the therapeutic activity of the other in a human subject." (page 6, lines 11-14; Guidance for Industry. *In vivo* drug metabolism/drug interaction studies - study design, data analysis and recommendations for dosing and labeling); "...upon administration of two drugs to treat a disease, it is unpredictable what change will occur in the negative side

profile of each drug." (page 6 lines 22-24; Guidance for Industry. *In vivo* drug metabolism/drug interaction studies - study design, data analysis and recommendations for dosing and labeling); and "…it is accurately difficult to predict when the effects of interaction between the two drugs will become manifest." (page 6, lines 26-28; Guidance for Industry. *In vivo* drug metabolism/drug interaction studies - study design, data analysis and recommendations for dosing and labeling). Accordingly, applicants submit that Polman does not support the co-administration of riluzole and glatiramer acetate for the treatment of multiple sclerosis as recited in the pending claims and that the first claimed technical feature is a contribution over the prior art and therefore constitutes a special technical feature as defined in PCT Rule 13.

Applicants therefore respectfully assert that two or more independent and distinct inventions have not been claimed in the subject application because the groups are not independent under M.P.E.P. §802.01. Therefore, restriction is improper under 35 U.S.C. §121.

Additionally, applicants point out that under M.P.E.P. §803, the Examiner must examine the application on the merits, even though it includes claims to distinct inventions, if the search and examination of an application can be made without serious burden. There are two criteria for a proper requirement for restriction, namely (1) the invention must be independent and distinct; AND (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants maintain that there would not be a serious burden on the Examiner if restriction were not required. A search of prior art with regard to any of Groups I and II would identify art for the other Groups. Since there is no serious burden on the Examiner to examine Groups I and II in the subject

application, the Examiner must examine the entire application on the merits.

No fee is deemed necessary in connection with the filing of this Amendment. However, if any additional fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invite the Examiner to telephone them at the number provided below.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Gary J. Gershik May 30, 2008

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